UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents
United States Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450
www.uspto.gov

OCT 27 2010

Office of Regulatory Policy
Food and Drug Administration
10903 New Hampshire Ave., Bldg. 51, Rm. 6222
Silver Spring, MD 20993-0002

Attention: Beverly Friedman

This is in regard to the application for patent term extension for U.S. Patent No. 6,034,267 filed by PhotoCure ASA under 35 U.S.C. § 156 on September 20, 2004.

The Federal Circuit decided that U.S. Patent No. 6,034,267 was eligible for patent term extension under 35 U.S.C. § 156. The dispute involved compliance with section 156(a)(5)(A). The position of the USPTO was that Metvixia was not the first permitted commercial marketing or use of the product as required by section 156(a)(5)(A) based on the theory that the same active moiety of Metvixia as was also present in a previously approved product, Levulan. The position of PhotoCure was that the statute does not refer to "active moiety," rather the statute refers to active ingredient. PhotoCure asserted that the active ingredient of Metvixia is different than the active ingredient of Levulan. In *Photocure v. Kappos*, 603 F.3d 1372 (Fed. Cir. 2010), the court relied on its previous decision in *Glaxo v. Quigg,* 894 F.2d 392 (Fed. Cir. 1990) (*Glaxo II*) for its determination of eligibility of Photocure's Metvixia product. Specifically, the Federal Circuit in *Photocure* stated that "[i]n *Glaxo* this court held that 'product' in §156(a) means the product that is present in the drug for which federal approval was obtained," *Id.* at 1376. (citing to *Glaxo II* at 894 F.2d at 393–95). Thus, *Glaxo II* is highly instructive in determining when an active ingredient, which may contain the same active moiety as a previously approved active ingredient, is eligible for extension.

In *Glaxo II*, the Federal Circuit affirmed the district court's determination that a patent which claimed an ester of cefuroxime was eligible for extension regardless of previous approvals of two salts of cefuroxime. *Glaxo II* at 393. Although the *Glaxo II* court did not explicitly set forth its rationale for determining that the patent was eligible for extension under 156, in affirming the district court, the Federal Circuit implicitly adopted the district court's rationale. There, the district court in *Glaxo v. Quigg*, 706 F. Supp 1224 (E.D. Va. 1989) (*Glaxo I*) framed the rationale for eligibility as:

> the question sharply presented is whether the "product" referred to in (a)(5)(A) is cefuroxime axetil, on the one hand, or cefuroxime, the parent acid on the other. The answer to this question turns on the statutory definition of "product." Subsection (f) of Section 156 defines "product" as "a drug product," which, in turn, is defined as follows:
>
> > (2) The term "drug product" means the active ingredient of a new drug, antibiotic drug, or human biological product

> (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act) including any salt or ester of the active ingredient, as a single entity or in combination with another active ingredient.
>
> *35 U.S.C. §156(f)(2).*
>
> The central question then is whether the active ingredient of Ceftin Tablets is the ester cefuroxime axetil or the parent acid cefuroxime. If the former is true, plaintiff is entitled to an extension of its patent term. If the latter is true, then no extension would be warranted because the FDA has previously approved NDA's for Zinacef and Kefurox, two sodium salts of cefuroxime.

Glaxo I at 1227.

Additionally, the *Photocure* court pointed out that they held in *Hoechst-Roussel Pharms., Inc. v. Lehman*, 109 F.3d 756, 759 (Fed. Cir. 1997) that "[f]or purposes of patent term extension, this active ingredient must be present in the drug product when administered." *Photocure* at 1376. Thus, the active ingredient of Photocure's Metvixia product is methylaminolevulinate hydrochloride, because that is the substance physically present in the final dosage form.

Applying the *Hoeschet* and *Glaxo I* analyses here, the active ingredient of Metvixia is methyl aminolevulinate hydrochloride. Neither it, nor any salt or ester of methyl aminolevulinate hydrochloride has been previously approved by FDA. Because no salt or ester of methyl aminolevulinate hydrochloride had been approved prior to the approval of Metvixia, the grant of permission to commercially market or use Metvixia is the first permitted commercial marketing or use of the product/active ingredient as required by section 156(a)(5)(A). Accordingly, the '267 patent is eligible for extension under the provisions of section 156.

Based on the Federal Circuit's finding that the '267 patent is eligible for extension, the assistance of your Office is requested in confirming that the product identified in the application, METVIXIA® (methylaminolevulinate hydrochloride), has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period beginning on the date the product was approved. Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, or a method of manufacturing or use of such a product, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent would be eligible for extension of the patent term under 35 U.S.C. § 156.

Inquiries regarding this communication should be directed to the undersigned at (571) 272-7755 (telephone) or (571) 273-7755 (facsimile).

Mary C. Till
Legal Advisor
Office of Patent Legal Administration
Office of the Associate Commissioner
for Patent Examination Policy

cc: Kenyon & Kenyon
One Broadway
New York, NY 10004